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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|-------------------------|------------------|
| 09/918,365 | 07/30/2001 | Eugene T. Michal | ACS 55933 | 1073 |
| 7590 07/26/2004 | | | EXAMINER | |
| CHARLES E. RUNYAN JR. PH.D SQUIRE, SANDERS & DEMPSEY LLP ONE MARITIME PLAZA, SUITE 300 SAN FRANCISCO, CA 94111-3492 | | | MICHENER, JENNIFER KOLB | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1762 | |

DATE MAILED: 07/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|---|--------------------------------------|--|
| Office Action Summary | Application No. 09/918,365 | Applicant(s) MICHAL ET AL. | |
| | Examiner Jennifer K. Michener | Art Unit 1762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 22 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 1-14 and 19-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input checked="" type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Newly-amended independent claims 1 and 34 are now directed to non-elected species distinct from the invention originally examined for the following reasons: claims 1 and 34 now require the thrombogenic material to comprise a surfactant-bound moiety, a requirement of non-elected claim 35, which encompasses the non-elected species of TDMA- and benzalkonium-heparins of claim 36 (see also, Interview Summary).

Since applicant has received an action on the merits for the originally elected species of unfractionated heparin, this species has been constructively elected by original presentation for prosecution on the merits. Accordingly, originally examined claims 1-14 and 34 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

Even though claim 13, depending on claim 1, remains directed to the originally-elected species of unfractionated heparin, this species is now in conflict with the new requirement of claim 1. Therefore, claim 13 is withdrawn with claim 1 and the other claims depending thereon.

In addition, the non-elected claims of the previous office action, namely 19-33, 35-46, remain withdrawn from consideration. Claims 47-79 have been canceled.

Therefore, elected claims 15-18 are examined below.

Specification

2. The objection to the title has been withdrawn in light of Applicant's amendment.

Claim Rejections - 35 USC § 112

3. The rejection of claims 1-18 and 34 under 35 U.S.C. 112, second paragraph, has been withdrawn in light of definitions provided by the instant specification.

Double Patenting

4. Claims 1-18 and 34 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 and 14 of U.S. Patent No. 6,221,425 and claims 1-17 of U.S. Patent No. 6,656,517. Examiner maintains the rejection of the previous office action.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 15-17 are rejected under 35 U.S.C. 102(b) as being anticipated by Cahalan et al. (US Pat. 5,607,475).

The rejection of claims 15-17 is maintained for those reasons outlined in the previous office action. The newly-added limitation of claim 15 is addressed in the previous office action regarding end-immobilization (see also, Response to Arguments section).

The rejection of claims 1-3, 5, 7, and 11-12 is withdrawn in light of the species election by prior presentation, as outlined above. For the purposes of appeal, Examiner notes that this rejection would be reinstated if the new limitation of claim 1 were removed.

7. Claims 15-17 are rejected under 35 U.S.C. 102(e) as being anticipated by Michal et al. (U.S. 6,287,285 B1).

The rejection of claims 15-17 is maintained for those reasons outlined in the previous office action. The newly-added limitation of claim 15 is addressed in the previous office action regarding end-immobilization.

The rejection of claims 1-12 and 34 is withdrawn in light of the species election by prior presentation, as outlined above. For the purposes of appeal, Examiner notes that this rejection would be reinstated if the new limitations of claims 1 and 34 were removed.

Claim Rejections - 35 USC § 103

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

9. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cahalan et al.

The rejection of claim 18 is maintained for those reasons outlined in the previous office action.

The rejection of claim 14 is withdrawn in light of the species election by prior presentation, as outlined above. For the purposes of appeal, Examiner notes that this rejection would be reinstated if the new limitation of claim 1 were removed.

10. Claim 18 is rejected under 35 U.S.C. 103(a) as being obvious over Michal et al. The rejection of claim 18 is maintained for those reasons outlined in the previous office action.

The rejection of claim 14 is withdrawn in light of the species election by prior presentation, as outlined above. For the purposes of appeal, Examiner notes that this rejection would be reinstated if the new limitation of claim 1 were removed.

11. The rejection of claim 13 under 35 U.S.C. 103(a) as being unpatentable over either Cahalan or Michal in view of Hughes et al. has been withdrawn in light of the species election by prior presentation, as outlined above. For the purposes of appeal, Examiner notes that this rejection would be reinstated if the new limitation of claim 1 were removed.

Response to Arguments

12. Applicant's arguments filed 4/22/2004 have been fully considered but they are not persuasive.

Applicant argues that Cahalan lacks the step of preparing a base coat *mixture* because Cahalan teaches adhering a silane first and then the acrylate monomer, such that the silane does not *mix* with the monomer.

Examine disagrees. As outlined in the previous office action, Examiner has relied upon the acrylate monomer compound to teach the base coat, not the silane. Cahalan teaches that the acrylate monomer solution is a *mixture* of acrylic acid and acrylamide, which is polymerized to form a base coat layer, as required by Applicant's claim (see. Col. 5, lines 20-30, as outlined in the previous office action). Examiner further notes that there is no active application step in the claim defining when application occurs. Therefore, even the monomer application over a surface-bound silane, the teachings relied upon by Applicant, does meet the definition of "mixing" because the word mix means to "commingle", "merge", "to bring into close association", etc.

Regarding Michal, Applicant merely states that Michal fails to teach end-immobilization of the anti-thrombogenic material.

Examiner disagrees.

As outlined in the previous office action, the anti-thrombogenic agent of Michal is bound to the substrate via an amine group binding agent, which would become the end-group of the agent's chain, for attachment to functional groups of the grafting material on the substrate. Additionally, the therapeutic agents of Michal contain end-group amines (col. 8). Furthermore, the instant specification teaches that end-immobilization refers to the attachment of the amine groups directly to a support member via at least one

intermediate component, which is met by the method of Michal. This new limitation was therefore addressed in the previous office action. If the newly-added limitation "through a group that terminates the anti-thrombogenic material" was intended to require a specific amine-terminated species of heparin, Examiner notes that this type of heparin would constitute a new species.

Conclusion

13. Applicant's amendment necessitated any new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

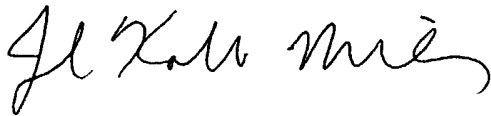
14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer K. Michener whose telephone number is (571)

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272-1424. The examiner can normally be reached on Monday through Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shrive P. Beck can be reached on 571-272-1415. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jennifer Kolb Michener
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July 23, 2004